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Laboratory managers must know the amount of labor and other resources expended to make effective resource decisions. Knowing the average cost per reportable result (ACPRR), the administrator can analyze "make versus buy" decisions, prepare a viable budget, and develop the department's strategic plan. Also, this information allows the administrator to evaluate new and existing instrumentation and procedures based on objective, quantitative data instead of intuition. The purpose of this project was to accurately determine the ACPRR for the Branch Medical Clinic Naval Training Center (BMCNTC), San Diego and compare the cost to a benchmarked reference laboratory. The productivity of the clinic laboratory staff and instrumentation was evaluated to determine which test volume was appropriate for the BMCNTC laboratory based on test frequency, cost, provider/patient needs, and instrumentation capability.

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An Evaluation Of Cost And Productivity In Laboratory Medicine Using Computer Simulation

Submitted to:

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LIST OF ABBREVIATIONS

PPS	Prospective Payment System
ACPRR	Average Cost Per Reportable Result
BMCNTC	Branch Medical Clinic, Naval Training Center
WMS	Workload Measurement System
RVU	Relative Value Unit
JLWG	Joint Laboratory Working Group
CBC	Complete Blood Count
HA	Hepatitis Assay
ABC	Activity Based Costing
FPG	Family Practice Group
CHCS	Composite Health Care System
MEPR	Medical Evaluation and Performance Report
NMCSD	Naval Medical Center San Diego

EXECUTIVE SUMMARY

Laboratory managers must know the amount of labor and other resources expended to make effective resource decisions. Knowing the average cost per reportable result (ACPRR), the administrator can analyze "make versus buy" decisions, prepare a viable budget, and develop the department's strategic plan. Also, this information allows the administrator to evaluate new and existing instrumentation and procedures based on objective, quantitative data instead of intuition. The purpose of this project was to accurately determine the ACPRR for the Branch Medical Clinic Naval Training Center (BMCNTC), San Diego and compare the cost to a benchmarked reference laboratory. The productivity of the clinic laboratory staff and instrumentation was evaluated to determine which test volume was appropriate for the BMCNTC laboratory based on test frequency, cost, provider/patient needs, and instrumentation capability.

INTRODUCTION

Conditions Which Prompted The Study

Health care costs have risen dramatically due to the interplay of such factors as increased patient severity, advanced technology, broader insurance coverage, and an increase in specially trained staff. Consequently, in 1995, health care spending is projected to account for 14.2 percent of the gross domestic product. The impact of these events has lead to changes in health care philosophy and the medical work environment (Hilborne 1996).

Hospitals and health care providers traditionally charged a fee for their services, and third party payers reimbursed them without questioning the cost or necessity of the services provided. With the fiscal pressures that have been put on the health care system, the focus is now on the financial bottom line. With the implementation of the Prospective Payment System (PPS) and the transition to managed care, the health care industry has changed dramatically. The system can no longer afford to pay for expensive medical care that cannot be clinically justified to a third party payor. Many health care systems now employ primary care gatekeepers to control patient access to the system. Utilization management, critical pathways, and case management are other techniques used to control the cost of care (Kongstvedt 1995).

The PPS and managed care environments also restrict utilization of clinical support services. Areas such as the laboratory, once considered a profit center, are now cost centers. The laboratory department is labor intensive and is the second largest consumer of supplies within the hospital.

Statement Of The Problem Or Question

Laboratory managers must know the amount of labor and other resources expended to make effective resource decisions. Knowing the average cost per reportable result (ACPRR), the administrator can analyze "make versus buy" decisions, prepare a viable budget, and develop the department's strategic plan. Also, this information allows the administrator to evaluate new and existing instrumentation and procedures based on objective quantitative data instead of intuition. The purpose of this project was to accurately determine the ACPRR for the Branch Medical Clinic Naval Training Center (BMCNTC), San Diego and compare the cost to that of a benchmarked reference laboratory. The productivity of the clinic laboratory staff and instrumentation were evaluated to determine which test volume was appropriate for the BMCNTC laboratory based on test frequency, cost, provider/patient needs, and instrumentation capability.

Literature Review

Determining the ACPRR sounds deceptively simple. Throughout pathology, the basic unit of work is the request, which represents a clinical question, and may require one or more tests to be performed (Broughton 1983). A test is defined as one analysis. However, one must operationally define what is being measured in a test before attempting to assign cost. ACPRR includes factors such as the cost of calibrators, quality control and the estimated number of repeat specimens due to dilutions (Wilkinson 1995).

To apportion expenditures between different work centers, all costs must be identified to include direct, indirect, fixed, and variable costs. Direct costs are defined as costs which are necessarily and exclusively incurred by performing a specified test at a particular time

(Broughton 1983). Whenever possible, testing is performed in a batch to achieve economies of scale, however, certain tests must be performed even when it is not economically efficient. For example, quality controls must be analyzed with each batch of blood alcohol specimens being tested. If the analyzer can accommodate one set of quality controls and five patient specimens per run, the system may be economically efficient. However, receipt of this request cannot be anticipated, making batch testing impractical. When one set of quality controls is used for each patient specimen tested, there is wasted analyzer capacity causing a variance in the direct costs associated with the test. Therefore, an average direct cost is calculated when determining ACPRR.

Indirect costs cannot be directly tied to the test, but are required to support the overall operation of the laboratory and its related infrastructure. Direct and indirect costs are considered to be either variable or fixed. Variable costs change in proportion with volume and fixed costs remain constant within a relative range of time and testing activity. Direct costs are relatively easy to determine within the laboratory. However, a fundamental problem in laboratory accounting is the allocation of indirect costs.

Broughton and Hogan chose not to allocate indirect costs to individual tests but to combine them, divide by the number of requests, and call the result a "handling charge per request". The total cost per test was considered to be the sum of the handling charge per request plus the direct costs of carrying out the test (Broughton 1983).

Pink, et. al., allocated laboratory costs to specific tests using two methods and examined their effects on laboratory costs. The first method, the workload measurement system (WMS), allocated laboratory costs to specific tests, using the allocation base WMS units. This method

assumes that both fixed and variable costs are linearly correlated with WMS units. The relative value unit (RVU) used WMS units to allocate those costs that are considered correlated with the WMS units, but uses other bases to allocate costs that are not considered correlated with WMS units. For example, the authors concluded a variable supply cost such as a reagent is correlated with WMS units and fixed labor cost, such as a supervisor's salary, is correlated with the number of laboratory tests performed (Pink 1994).

These methods make erroneous assumptions. The WMS, the RVU, and Broughton and Hogan's methods incorrectly assumes fixed costs correlate with volume. Fixed costs remain constant throughout a relevant range of testing and increase with volume only when additional labor or capital have to be added to support additional testing. When testing volume decreases, these costs do not decrease.

Tarbit developed a laboratory costing system that recovered all costs against tests, rather than using both tests and request charges. He considered methods of recovering costs of routine and emergency services, capital investment in equipment, instrument maintenance costs, and general hospital overhead. The Welcan unit system of workload measurement was applied to a range of test procedures. The Welcan workload measurement system, similar to the Canadian WMS unit, provided a schedule of unit values for procedures to reflect the average technical and aid time required to perform each test. One Welcan unit equals 1 minute of technical, clerical, and aide time (Tarbit 1990). The study found that Welcan unit values and locally derived analytical time per test did not reflect total resource consumption for the provision of numerous test procedures (Pink 1994).

In 1994, the Joint Laboratory Working Group (JLWG) developed a four step model to

determine cost per test. First, the administrator prioritized the costing efforts. This analysis was performed based on the Pareto Principle which states that 80 percent of test costs are generated by 20 percent of the test types and 80 percent of test volume is generated by 20 percent of the test types. Alternatively, one could choose to look at high cost, low volume tests which are approximately 5 percent of the tests performed or one could choose special tests which comprise approximately 5 percent of the test types.

The second step was to diagram the entire testing process from receipt of request to report of final results. This step illustrated the complexity of the testing process and helped the administrator track the associated direct and indirect costs.

Step three consisted of data collection. The administrator defined which data items were associated with the testing process and would collect them from various sources. The final step would be to determine the cost per test. Like the previously described methods, the JLWG method allocated direct and indirect costs based on testing volume (JLWG 1994).

Although this method would be relatively simple and easy to perform, it too was inherently inaccurate. Again, all costs were allocated based on volume, therefore, tests that were quick and simple to perform, received the same indirect cost allocation as time consuming, labor intensive testing. For example, assume a laboratory performed two types of tests in the following amount: 100 complete blood counts (CBCs) with $200 in direct costs and 100 Hepatitis Assays (HAs) with $500 in direct costs. Also assume the laboratory has $2000 in indirect costs. Using the JLWGs model, both the CBCs and the HAs are allocated $10 of indirect cost even though HAs are not fully automated and are extremely labor intensive. The cost per test are as follows:

Test	Percentage Indirect Cost	Total Indirect Cost	Allocated Indirect Cost	Direct Cost	Volume	Cost Per Test*
CBC	50%	$2000	$1000	$200	100	$12
HA	50%	$2000	$1000	$500	100	$15

To accurately determine the amount of indirect cost to be allocated to a particular test, activity based costing (ABC) can be used. ABC recognizes that costs are incurred by activities and by defining those activities, measuring them, and tying them back to specific tests, administrators could more accurately determine how much products actually cost and thus could make more informed decisions (Rao 1995). Using the previous example, if the relatively simple CBC testing requires 20 percent of the overhead and the complexity of HA testing requires 80 percent of the overhead, ABC determines the cost per test as:

Test	Percentage Allocated Indirect Cost	Total Indirect Cost	Allocated Indirect Cost	Direct Cost	Volume	Cost Per Test*
CBC	20%	$2000	$400	$200	100	$6
HA	80%	$2000	$1600	$500	100	$21

This example illustrates how the JLWGs method inflated the cost of the CBC and under estimated the cost of the HA. Errors of this type can hamper the long term strategic planning efforts in the laboratory and ruin the short term budgeting process. The ABC method more accurately allocates all costs associated with testing.

*Cost Per Test = (Percentage of Allocated Indirect Cost x Indirect Cost) + Direct Cost

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Volume

METHOD AND PROCEDURES

To accurately measure the ACPRR, a four-step model is proposed. Step One: define activities. Activities were laboratory tests performed at Branch Medical Clinic Naval Training Center (BMCNTC). Step Two: define cost drivers. Cost drivers were defined as the events that caused a change in the total cost of an activity. The more this activity occurred, the higher the costs. This included the number of providers who could order tests at the clinic, test methodology, and available instrumentation. Step Three: determine activity volumes and their costs. The average time per test performed at BMCNTC was measured. The volume of testing performed at the clinic was determined based on historical data available in Composite Health Care System databases. Direct and indirect costs related to the laboratory at BMCNTC were then calculated. Step Four: activity rates were calculated, allocating indirect costs to appropriate activities. Activity Rate = Activity Costs / Activity Volume. Each product was charged with the costs per unit of activity when it was used. This method calculated the price of the unit based on the cost per unit of indirect and direct activity used (Internet).

The Simulation Model

Simulation is a tool used to build models of complex systems and evaluate them in ways that traditional methods of analysis cannot. Not only does simulation allow the user to go easily beyond the general limits of elementary comprehension when analyzing a system, it gives a good picture of how the system behaves and what factors represent real performance indicators under different circumstances (Keller 1991). Simulation models have been used to investigate the relationships between system configuration, patient flows, and resource allocation decisions

(Cohen 1980). Single or multiple variables are modified and their effects on the system are visualized and/or calculated, enabling the modeler to see the impact of policy decisions in simulated time without having to invest valuable resources.

Simulation analysis has been utilized by many researchers to investigate various aspects of hospital operation including outpatient services. Hancock determined the number of procedures that were performed in nineteen ancillary departments on a daily basis (Hancock 1984). It was decided that the proposed occupancy of a new hospital facility should not be based on the maximum possible number of procedures. Therefore, simulation was used to smooth the daily departmental loads through sensitivity analysis on variables such as (1) admission day of elective patients, (2) urgent inpatient loads, and (3) outpatient loads. Amladi developed a simulation model which was utilized to size and plan a proposed outpatient surgical facility (Amladi 1984). Given a projected patient demand, the purpose of the analysis was to optimize patient waiting time based on a quality criterion and facility size based on cost considerations (Levy 1989).

MedModel©, a discrete, Windows© based event simulator, was used to evaluate different model constructs within the laboratory at BMCNTC. Potential system modifications included specimen and process flow, test variety, number of staff available, number of providers requesting laboratory tests, hours of laboratory operation, and number of staff hours. The modeler defined specimen interarrivals and event durations, while MedModel© stochastically influenced these model parameters. Animation was used to visualize the system in action, clearly illustrating specimen queues, and helping to validate the model. Model output identified misallocated staff and resources by calculating resource productivity. Time was accelerated to view an entire clinic day in a few seconds or slowed to visualize the process as it occurred. The

model was replicated to simulate variation in laboratory performance that randomly occurred over time (MedModel©, User's Guide).

Ethical Concerns

All data collected for this project were limited to tests that were ordered and visits within defined clinics. No patient names or social security numbers were used in the analysis.

FINDINGS AND UTILITY OF RESULTS

Integrating the results of the simulation with the ABC model, an ACPRR was calculated and the result compared to the price charged by a civilian benchmarked laboratory. This comparison provided valuable insight into resource allocation decisions. However, final managerial decisions should not be made on an economic basis alone. Certain laboratory tests must be performed at the clinic for the convenience of both the provider and the patient. If a provider had the results of certain laboratory tests, treatment could be initiated before the patient left the clinic. This would increase provider and patient satisfaction and increase the chance that the patient would receive prompt, effective treatment. Purely economic decisions would be inappropriate for these types of tests. However, many test results are not necessary for short term treatment decisions, but are used for documentation or monitoring purposes. These tests should be looked at carefully to determine the most cost effective testing venue.

ACPRR information and laboratory productivity would allow the administrator to combine testing capabilities to achieve economies of scope. This would produce efficiencies that could not be achieved without accurate cost and productivity information. Performing tests on a single analyzer decreases maintenance costs, supply costs, and ordering costs. The money saved could

be used for other purposes to improve patient care. Other information could be gleaned, such as possible savings gained through staff reduction (lower indirect costs), make versus buy decisions, and outsourcing. Knowledge gained from this project will provide a benchmark for Tricare contract services.

The Clinic

The ambulatory care clinic at Naval Training Center, San Diego offered a complete range of healthcare services to support their population of young, healthy, active duty patients. These services included: Physical Medicine, Gynecology, Psychiatry, Psychology, Primary Care, Medical Exam, Optometry, Community Health, Occupational Health, Immediate Care, Physical Therapy, and Neuromusculoskeletal. In September 1996, the clinic added a Family Practice Group (FPG) to increase the utilization of the clinic and increase access to Tricare Prime beneficiaries. It was anticipated that the increase in the number of patients, the change in patient mix, and the increased scope of service offered could have a significant impact on laboratory workload at the clinic.

Because the FPG concept was new, many patients were not aware of this increased access at BMCNTC and many appointments were not being utilized. Therefore, the number of anticipated clinic visits had to be estimated. According to the Department Head of the FPG, providers were expected to see twenty to twenty five patients per day and they were staffed with six family practice and two internal medicine physicians. Using the number and mix of providers, the FPG could accommodate 190 visits per day. See Table 1.

Table 1.--Family Practice Group At Less Than Full Capacity

Physician Type	Visits/day	# Providers	Max Visits/Day
Family Practice	25	4	150
Internal Medicine	20	2	40
Total Visits Per Day			190

The staff allocated fifteen minute appointments per patient for family practice physicians, twenty minute appointments for internal medicine patients, and forty minute appointments for new internal medicine patients. If the FPG increased its visit capacity to fully utilize all appointments in an eight hour day, there was a potential maximum of 240 patient visits per day as described in Table 2.

Table 2.--Family Practice Group At Full Capacity

Physician Type	Min/visit	Visits/hr	Visits/day	# Providers	Max Visits/Day
Family Practice	15	4	32	6	192
Internal Medicine	20	3	24	2	48
Total Visits Per Day					240

The Laboratory

The laboratory at BMCNTC was staffed with five full time technicians with varying amounts of experience, training, and seniority. Four of the technicians were fully trained in all aspects of laboratory medicine and were qualified to perform all types of analysis. The fifth technician did not have the required training to perform testing; his tasks were limited to registering patients at the reception desk and performing phlebotomy. Often there was a laboratory student available who could analyze specimens and perform phlebotomy under supervision. Since the availability of a student was not assured, this technician was not incorporated into the model.

The laboratory was open Monday through Friday from 7:30 am until 5 pm. Laboratory

hours were extended until 6:30 pm on Wednesday to accommodate the FPG's extended hours. Two technicians arrived at 6:30 am to perform daily quality control, calibration, and equipment maintenance. These early morning technicians departed at 4:00 pm. The remainder of the staff arrived at 7:30 am and worked until the clinic closed at 5:00 pm. On Wednesday, one technician arrived at 11:30 am and stayed until 6:30 pm.

The clinic promoted a "family friendly" work environment and encouraged departments to extend daily work hours one hour per day within an 80 hour two week period to allow a day off on alternate Fridays. Most departments within the clinic, including the laboratory, staggered their personnel to take advantage of this policy. Based on the laboratory's hours of operation, the technicians worked 76.5 hours every two weeks. The technician who worked the late Wednesday shift worked 72.5 hours every two weeks.

The laboratory at BMCNTC performed a complete set of analysis appropriate for an ambulatory clinic. See Table 3. Chemistry tests were performed on a Synchron CX5 Delta which was leased at a cost of $4,100 per month. CBCs and reticulocyte counts were run on the Coulter MAXM at a monthly lease cost of $2,865 for the CBCs and $148 per month for the reticulocyte capability. Urinalysis was performed on the Boehringer Mannheim Chemstrip ® Urine Analyzer. See Table 4 for the projected testing volume for these instruments. Reagents, supplies, calibrators, controls, and customer service support were included in the monthly lease price, with one exception, as urine controls were purchased separately.

All other testing was performed manually. Equipment used in support of this nonautomated testing included the use of microscopes, incubators, rotators, and refrigerators. This equipment had been purchased by the clinic and there was no other cost associated with its other than

routine maintenance.

Table 3.--Tests Offered At BMCNTC

Automated Tests	Nonautomated Tests
Chemistry Panel	HCG - qualitative
Complete Blood Cell Count	ESR
Reticulocyte Count	Monospot
Urinalysis	Throat culture
	Urine culture
	Wound culture
	GC Culture
	Occult blood (stool)
	Gram stain
	Slide test, KOH
	Stain, fecal WBC
	Slide test, saline
	RPR

Table 4.--Monthly Lease Agreement Cost Based On Projected Usage

Instrument	Monthly Projected Usage	Monthly Cost
Synchron CX5 Delta	5000*	$4,100
Coulter MAXM		
CBCs	1200	$2,865
Reticulocyte	100	$148
Boehringer Mannheim	600	$506
Chemstrip ®		

*analytes

Two types of data were used for this simulation project: task events and volume statistics. Tasks were operationally defined as events that engaged the technicians for a finite period of time. Each event had a distinct beginning point and end point. These events were measured by the modeler using direct observation. Table 5 lists the events that were measured. If a test was not performed during the data collection period, technician estimates were used. Only a few

events were not observed and they occurred so infrequently that it is believed that their impact had a insignificant effect on the model. All observed data were analyzed using Stat::Fit$_{TM}$, a statistical distribution fitting software package, to determine the appropriate statistical distribution. Normal distributions were used when there were no observation data available. See Evans 1993 for a explanation of the statistical distributions used in the model.

Table 5.--Tasks Measured By Direct Observation

Patient check in	Monospot
Phlebotomy	ESR
Daily quality control	Throat culture
Equipment maintenance	Urine culture
Equipment calibration	Wound culture
Chemistry Testing	GC Culture
Complete Blood Cell Count	Occult blood (stool)
Reticulocyte	RPR
Urinalysis	HCG - qualitative

Volume statistics were derived from Composite Health Care System (CHCS) data sources. Twelve months of test data were analyzed by test type to approximate the representative number of tests performed and to determine the average number of tests ordered per day. See Table 6.

Table 6.--Tests Performed Each Day

Test	# Per Day
Chemistry panel*	16
CBC	12
Urinalysis	12
RPR	11
Urine HCG	6
Throat culture	2
ESR	2
Occult blood	1
Urine culture	1
GC culture	1
Gram stain	1
Monospot	1
Slide test, KOH	<1
Stain, fecal wbc	<1
Slide test, saline	<1
Wound culture	<1
Reticulocyte count	<1

*At the time of data collection chemistry panels were being tested at the Main Laboratory at NMCSD. The model was built assuming that chemistry testing would be performed at BMCNTC.

The Simulation Model

Patients arrived at the main entrance to the laboratory where they were greeted by a technician who determined which tests were ordered by the provider. If the patient had a microbiology or a urinalysis specimen, the technician took the specimen, completed the computerized check in process, and printed the required labels. The patient then left the laboratory. The specimen was transported to a central processing area in the laboratory by the receiving technician. If the patient had to have a phlebotomy performed, the technician completed the computerized check in process, printed the appropriate labels and directed the patient to the blood draw room.

When patients arrived in the blood draw room, they sat in a chair and waited for the phlebotomist to draw their blood. Upon completion of this process, the technician labeled the specimens and puts a bandage on the patient who then left the laboratory. All specimens were taken by the technician to the appropriate location within the laboratory for testing.

Chemistry specimens were allowed to clot prior to centrifugation and processing. Each chemistry request was checked prior to analysis to determine which analytes had been ordered. The ordered tests were selected for analysis by the Synchron CX5 Delta. CBC specimens were checked for clots prior to analysis on the Coulter MAXM. If the automated differential was abnormal, a slide was made and a manual differential was performed. Urinalysis specimens were observed for color and clarity prior to analysis using the Boehringer Mannheim Chemstrip ® Urine Analyzer. After analysis, if the protein concentration exceeded a defined amount, a confirmatory test was preformed. Each urine specimen was centrifuged and the sediment was analyzed by a technician. All automated results were evaluated by the technician to determine if the provider needed to be called or if the test had to be repeated. Since no data were available, repeat analyses were not incorporated into the model. Nonautomated testing was performed according to the standard operating procedure and/or manufacturer's instructions.

The model was built to reflect the staffing of five technicians with a work week consisting of Monday through Friday and four weeks were considered to be one month. Active duty military staff members accrued 2.5 days of leave per month. This leave requirement plus four hours of administrative time per month were accounted for in the model. Although four hours of administrative time per month was conservative given the numerous military activities that are required of active duty members, the additional time required to perform these functions could be

accomplished since the technicians do not work a forty hour week. The model also assumed that all leave was taken during working hours and no leave was taken on the weekends. This assumption provided a "worst case" scenario and prevented an underestimate in the final analysis.

The model reflected three scenarios. The first scenario, the status quo model, assumed that tests were ordered based on the volume of testing reflected in Table 6 which were collected prior to the opening of the FPG. Scenario two assumed that the FPG served 190 patients per day and scenario three assumed that there was no excess capacity within the FPG and there were 240 visits per day. Each scenario was replicated twelve times to reflect one year of laboratory operation.

The assumption was made that there is a correlation between the number of clinic visits and the number of laboratory tests requested. One year of BMCNTC laboratory data were compared with the same time period of provider visits. Providers that did not generate a significant number of laboratory requests, i.e., physical therapists, psychologists, optometrists, etc., were not included in clinic visit data. Volume statistics were also analyzed after the opening of the FPG to assess the impact of that service on the laboratory and it was noted that the number of laboratory tests actually fell during this period. However, caution must be used when evaluating this information. The number of operational FPG clinic days was limited, less than two months, and the small sample size could easily bias the results.

Further analysis was performed looking at the number of Internal Medicine visits and the number of laboratory tests ordered from that Medical Expense and Performance Reporting (MEPR) System code. As one would expect, the number of laboratory tests generated by

Internal Medicine was higher than those associated with BMCNTC. However, these numbers were not used in the model because the number of internal medicine visits was relatively small compared to the number of family practice visits within the FPG. Also, the testing generated from the internal medicine MEPR code reflects all subspecialties, i.e., cardiology, gastroenterology, endocrinology, etc. and it is believed that these patients generate more requirements for laboratory procedures than would be seen at the FPG at BMCNTC. In the final analysis, the number of laboratory tests defined in Table 6 was fairly representative of the number of specimens that were observed during the data collection period and may actually may be slightly overestimated. This bias was considered preferable for this study.

The Alternate Model

One goal of this study was to determine if laboratory testing should be performed on site or sent to a reference laboratory for testing. If laboratory testing was not performed at BMCNTC, a location had to be available to allow patients to have their blood drawn and to drop off specimens for analysis. Staff have to be available to perform the required phlebotomy, receive specimens, package specimens for the reference laboratory, and to receive completed test results. An alternate model was built in which there was no testing performed on site and specimens were collected, packaged, and shipped to a reference laboratory.

This model was staffed with three technicians who work the same hours as in the previous model. Patients arrived at the main entrance to the laboratory where they were greeted by a technician who determined which tests had been ordered by the provider. If the patient had a microbiology or a urinalysis specimen, the technician took the specimen, completed the computerized check in process, and printed the required labels. The patient then left the

laboratory. The specimen was transported to a central processing area in the laboratory by the receiving technician. If the patient had to have a phlebotomy performed, the technician completed the computerized registration process, printed the appropriate labels and directed the patient to the blood drawing room.

When patients arrived in the blood drawing room, they sat down and waited for the phlebotomist to draw their blood. Upon completion of this process, the technician labeled the specimens and put a bandage on the patient who left the laboratory. Once per day the specimens were prepared for shipping to the reference laboratory. This model was evaluated based on the previously described three scenarios and replicated twelve times each.

Model Validity

Face validity was established using MedModel's© animation. The modeler, a medical technologist, was able to validate the processes as they occurred. After viewing the animation, it was obvious that the simulated processes resembled clinic reality as it existed during the data collection period and the level of detail was sufficient to make administrative decisions. The model was also validated using sensitivity analysis. When the scenarios increased the number of tests that had to be performed, staff utilization increased in appropriate amounts. When the alternate model ran, the utilization decreased as was expected.

Cost Allocation

A general overview of direct labor, consumables, and clinic overhead are listed in Table 7. Labor was allocated over the monthly operational time of the clinic and leases were allocated to the monthly volume of tests that they supported. Urine, HCG, and RPR quality control was performed each day the clinic was open, therefore, these costs were allocated as monthly

consumables. Microbiology supplies were ordered in a fixed quantity per month; its costs were allocated as a fixed cost to the number of microbiology tests that were performed. The clinic equipment was depreciated assuming a five year straight line depreciation with no salvage value.

True clinic overhead was derived from the Medical Evaluation and Performance Report (MEPR) Summary Report. All expenses that were allocated to the laboratory based on Naval Medical Center, San Diego's (NMCSD) step down process were considered true overhead for the laboratory cost center. Refrigerators were required to store reagents and specimens but were not directly tied to any testing procedure, therefore, they were considered part of true clinic overhead. Table 8 describes the costs allocated by general test type.

Table 7.--Cost Allocation Overview

Activity	Cost Per Month
Labor	$14,918.40
Leases	
Synchron CX5 Delta	$4,100
Coulter MAXM	$2,865
Reticulocyte	$148
Boehringer Mannheim Chemstrip ®	$506
Overhead Consumables	
UA Controls	$33.60
HCG Controls	$153.60
RPR Controls	$134.40
Microbiology supplies	$132.65
Depreciated Equipment	
RPR Rocker	$24.17
Microbiology incubator	$83.33
Bar code reader	$62.50
Refrigerators (3)	$250.00

Table 8.--Overhead Allocation By Test Type Per Month

True Clinic Overhead:	
Clinic	$6,777.59
Refrigerators (depreciation)	$250.00
Total	$7,027.59
Microbiology Overhead	
Microbiology supplies	$132.65
Microbiology incubator (depreciation)	$83.33
Total	$215.98
RPR Overhead	
RPR Controls	$134.40
RPR Equipment (depreciation)	$24.17
Total	$158.57
Chemistry Overhead	
Synchron CX5 Delta	$4,100.00
Bar Code Reader	$62.50
Maintenance for Bar Code Reader	$52.08
Total	$4,214.58
Urinalysis Overhead	
Boehringer Mannheim	
Chemstrip ®	$506.00
UA controls	$33.60
Total	$539.60

Results

The results were analyzed to determine the ACPRR. See Tables 9,10, and 11.

Table 9.--Average Cost Per Reportable Result: Scenario 1

Test	# Of Tests	Avg Min In Operation	Total # of Operating Minutes	Clinic Overhead Cost Per Operating Minute	Clinic Overhead Cost Per Test	Lease Overhead	Direct Consumable &/or Lease Per Test*	Direct Labor Minutes	Total # Direct Labor Minutes	Direct Labor Cost Per Minute	Direct Labor Per Test	ACPRR
Chem	292	49.92	14576.64	.24	11.98	4214.58	14.43	15.45	4511.40	.81	12.45	38.87
Urinalysis	232	15.26	3540.32	.24	3.66	539.60	2.32	16.54	3837.28	.81	13.33	19.32
RPR	193	21.33	4116.69	.24	5.12	158.57	0.82	15.61	3012.73	.81	12.58	18.52
Retic	20	52.76	1055.20	.24	12.66	148.00	7.40	19.04	380.80	.81	15.35	35.41
CBC	221	13.33	2945.93	.24	3.20	2865.00	12.96	16.61	3670.81	.81	13.39	29.55
ESR	24	62.05	1489.20	.24	14.89	N/A	insignificant	13.33	319.92	.81	10.74	25.64
Diff	39	11.50	448.50	.24	2.76	N/A	insignificant	17.78	693.42	.81	14.33	17.09
Urine Cul	12	2.03	24.36	.24	0.49	N/A	2.96	6.14	73.68	.81	4.95	8.39
Throat Cul	38	2.01	76.38	.24	0.48	N/A	2.96	6.12	232.56	.81	4.93	8.37
Wound Cul	1	1.81	1.81	.24	0.43	N/A	2.96	5.92	5.92	.81	4.77	8.16
GC Cul	22	2.02	44.44	.24	0.48	N/A	2.96	6.13	134.86	.81	4.94	8.38
Gram Stain	16	8.11	129.76	.24	1.95	N/A	insignificant	12.22	195.52	.81	9.85	11.80
HCG	146	2.99	436.54	.24	0.72	N/A	1.40	7.10	1036.60	.81	5.72	7.84
Occult Bld	20	1.97	39.40	.24	0.47	N/A	2.00	6.08	121.60	.81	4.90	7.37
Monospot	13	5.06	65.78	.24	1.21	N/A	1.70	9.17	119.21	.81	7.39	10.31
KOH Prep	8	4.79	38.32	.24	1.15	N/A	insignificant	8.90	71.20	.81	7.17	8.32
Fecal Wbc	3	5.31	15.93	.24	1.27	N/A	insignificant	9.42	28.26	.81	7.59	8.87
Slide, saline	7	4.94	34.58	.24	1.19	N/A	insignificant	9.05	63.35	.81	7.29	8.48
Total			29079.78									

Table 10.--Average Cost Per Reportable Result: Scenario 2

Test	# Of Tests	Avg Min In Operation	Total # of Operating Minutes	Clinic Overhead Cost Per Operating Minute	Clinic Overhead Cost Per Test	Lease Overhead	Direct Consumable & Lease Per Test*	Direct Labor Minutes	Total # Direct Labor Minutes	Direct Labor Cost Per Minute	Direct Labor Per Test	ACPRR
Chem	624	49.92	31150.08	0.12	5.75	4214.58	6.75	15.45	9640.80	0.38	5.92	18.42
Urinalysis	488	15.26	7446.88	0.12	1.76	539.60	1.11	16.54	8071.52	0.38	6.33	9.20
RPR	425	21.33	9065.25	0.12	2.46	158.57	0.37	15.61	6634.25	0.38	5.98	8.81
Retic	25	52.76	1319.00	0.12	6.08	148.00	5.92	19.04	476.00	0.38	7.29	19.29
CBC	476	13.33	6345.08	0.12	1.54	2865.00	6.02	16.61	7609.36	0.38	6.36	13.92
ESR	47	62.05	2916.35	0.12	7.15	N/A	insignificant	13.33	626.51	0.38	5.10	12.26
Diff	79	11.50	908.50	0.12	1.33	N/A	insignificant	17.78	1404.62	0.38	6.81	8.13
Urine Cul	24	2.03	48.72	0.12	0.23	N/A	2.96	6.14	147.36	0.38	2.35	5.54
Throat Cul	83	2.01	166.83	0.12	0.23	N/A	2.96	6.12	507.96	0.38	2.34	5.53
Wound Cul	1	1.81	1.81	0.12	0.21	N/A	2.96	5.92	5.92	0.38	2.27	5.43
GC Cul	44	2.02	88.88	0.12	0.23	N/A	2.96	6.13	269.72	0.38	2.35	5.54
Gram Stain	32	8.11	259.52	0.12	0.93	N/A	insignificant	12.22	391.04	0.38	4.68	5.61
HCG	289	2.99	864.11	0.12	0.34	N/A	1.40	7.10	2051.90	0.38	2.72	4.46
Occult Bld	45	1.97	88.65	0.12	0.23	N/A	2.00	6.08	273.60	0.38	2.33	4.56
Monospot	26	5.06	131.56	0.12	0.58	N/A	1.70	9.17	238.42	0.38	3.51	5.79
KOH Prep	16	4.79	76.64	0.12	0.55	N/A	insignificant	8.90	142.40	0.38	3.41	3.96
Fecal Wbc	6	5.31	31.86	0.12	0.61	N/A	insignificant	9.42	56.52	0.38	3.61	4.22
Slide, saline	13	4.94	64.22	0.12	0.57	N/A	insignificant	9.05	117.65	0.38	3.47	4.03
Total			60973.94						38962.55		76.81	

Table 11.--Average Cost Per Reportable Result: Scenario 3

Test	# Of Tests	Avg Min In Operation	Total # of Operating Minutes	Clinic Overhead Cost Per Operating Minute	Clinic Overhead Cost Per Test	Lease Overhead	Direct Consumable & Lease Per Test*	Direct Labor Minutes	Total # Direct Labor Minutes	Direct Labor Cost Per Minute	Direct Labor Per Test	ACPRR
Chem	729	49.92	36391.68	0.10	4.95	4214.58	5.78	15.45	11263.05	0.33	5.14	15.87
Urinalysis	561	15.26	8560.86	0.10	1.51	539.60	0.96	16.54	9278.94	0.33	5.51	7.98
RPR	498	21.33	10622.34	0.10	2.11	158.57	0.32	15.61	7773.78	0.33	5.20	7.63
Retic	30	52.76	1582.80	0.10	5.23	148.00	4.93	19.04	571.20	0.33	6.34	16.50
CBC	540	13.33	7198.20	0.10	1.32	2865.00	5.31	16.61	8969.40	0.33	5.53	12.16
ESR	57	62.05	3536.85	0.10	6.15	N/A	insignificant	13.33	759.81	0.33	4.44	10.59
Diff	88	11.50	1012.00	0.10	1.14	N/A	insignificant	17.78	1564.64	0.33	5.92	7.06
Urine Cul	29	2.03	58.87	0.10	0.20	N/A	2.96	6.14	178.06	0.33	2.04	5.20
Throat Cul	96	2.01	192.96	0.10	0.20	N/A	2.96	6.12	587.52	0.33	2.04	5.20
Wound Cul	1	1.81	1.81	0.10	0.18	N/A	2.96	5.92	5.92	0.33	1.97	5.11
GC Cul	53	2.02	107.06	0.10	0.20	N/A	2.96	6.13	324.89	0.33	2.04	5.20
Gram Stain	37	8.11	300.07	0.10	0.80	N/A	insignificant	12.22	452.14	0.33	4.07	4.87
HCG	299	2.99	894.01	0.10	0.30	N/A	1.40	7.10	2122.90	0.33	2.36	4.06
Occult Bld	51	1.97	100.47	0.10	0.20	N/A	2.00	6.08	310.08	0.33	2.02	4.22
Monospot	29	5.06	146.74	0.10	0.50	N/A	1.70	9.17	265.93	0.33	3.05	5.25
KOH Prep	19	4.79	91.01	0.10	0.47	N/A	insignificant	8.90	169.10	0.33	2.96	3.44
Fecal Wbc	8	5.31	42.48	0.10	0.53	N/A	insignificant	9.42	75.36	0.33	3.14	3.66
Slide, saline	16	4.94	79.04	0.10	0.49	N/A	insignificant	9.05	144.80	0.33	3.01	3.50
Total									44817.52		66.78	

If the laboratory at BMCNTC did not perform its own testing, specimens could be sent to the NMCSD for analysis or a reference laboratory could be used. Since there was no cost information available from NMCSD, a reference laboratory was used as a cost benchmark.

A nationally known, accredited reference laboratory was contacted to determine how much it would charge to perform BMCNTC's laboratory testing. Table 12 compares the ACPRR at BMCNTC with the cost of purchasing the same test at a reference laboratory. The purchase price quoted is only an estimate and reflects the discount that would be realized given the volume of testing associated with each scenario.

Table 12.--Make Versus Buy

Test	ACPRR Scenario 1	ACPRR Scenario 2	ACPRR Scenario 3	Buy
Chem	$38.87	$18.42	$15.87	$9.37
Urinalysis	19.32	9.20	7.98	5.63
RPR	18.52	8.81	7.63	6.25
Retic	35.41	19.29	16.50	23.80
CBC	29.55	13.92	12.16	6.72
ESR	25.64	12.26	10.59	11.56
Urine culture	8.39	5.54	5.20	20.50
Throat culture	8.37	5.53	5.20	26.12
Wound culture	8.16	5.43	5.11	26.12
GC culture	8.38	5.54	5.20	24.70
HCG	7.84	4.46	4.06	8.75
Occult Blood	7.37	4.56	4.22	31.60
Monospot	10.31	5.79	5.25	25.60

The cost charged by the reference laboratory includes specimen pick up, all supplies, and next day results. If a test is needed before the next day, an extra $10 per test and an $18 transportation fee is charged. Based on the above information, the reference laboratory price per test for the high volume tests is considerably cheaper than the cost to perform the same analysis

at BMCNTC.

However, the price charged by the reference laboratory does not include the cost associated with having the space and staff available to draw patient's blood and accept microbiology and urinalysis specimens. Also, the clinic overhead cost that was allocated to the laboratory had to be distributed within BMCNTC. It is logical that those costs should be borne by the scaled down laboratory. The modified model was evaluated based on the three defined scenarios and Table 13 describes the modified ACPRR.

Table 13.–ACPRR: Scenario 1

Test Types	# Of Tests	Avg Min In Operation	Total # Of Test Operating Min	Overhead Cost Per Operating Min	Overhead Cost Per Test	Direct Labor Min	Total # Of Direct Labor Min	Direct Labor Cost Per Min	Direct Labor Per Test	ACPRR
UA	240	1,440	345,600	0.01	9.23	5.94	1,425.60	1.13	6.72	15.95
Micro	141	1,440	203,040	0.01	9.23	5.94	837.54	1.13	6.72	15.95
Phlebotomy	380	1,440	547,200	0.01	9.23	13.11	4,981.80	1.13	14.83	24.06
Total			1,095,840				7,244.94			

ACPRR: Scenario 2

Test Types	# Of Tests	Avg Min In Operation	Total # Of Test Operating Min	Overhead Cost Per Operating Min	Overhead Cost Per Test	Direct Labor Min	Total # Of Direct Labor Min	Direct Labor Cost Per Min	Direct Labor Per Test	ACPRR
UA	493	1,440	709,920	0.0032	4.58	5.94	2,928.42	0.56	3.33	7.91
Micro	275	1,440	396,000	0.0032	4.58	5.94	1,633.50	0.56	3.33	7.91
Phlebotomy	767	1,440	1,104,480	0.0032	4.58	13.11	10,055.37	0.56	7.35	11.93
Total			2,210,400				14,617.29			

ACPRR: Scenario 3

Test Types	# Of Tests	Avg Min In Operation	Total # Of Test Operating Min	Overhead Cost Per Operating Min	Overhead Cost Per Test	Direct Labor Min	Total # Of Direct Labor Min	Direct Labor Cost Per Min	Direct Labor Per Test	ACPRR
UA	557	1,440	802,080	0.0028	4.02	5.94	3,308.58	0.49	2.93	6.95
Micro	316	1,440	455,040	0.0028	4.02	5.94	1,877.04	0.49	2.93	6.95
Phlebotomy	873	1,440	1,257,120	0.0028	4.02.	13.11	11,445.03	0.49	6.46	10.48
Total			2,514,240				16,630.65			

Incorporating the cost of the modified laboratory with the price of reference laboratory testing, describes the total cost of purchasing laboratory service. Tables 14, 15, and 16 compare the true costs of performing the testing at BMCNTC versus having a reference laboratory perform the same tests based on the volume of testing that was anticipated by the three scenarios.

Table 14.--Total Laboratory Cost - Make Versus Buy: Scenario 1

Test	Volume	Make	Buy	Overhead Associated With Buy	Cost To Buy Per Test	Total Cost To Make	Total Cost To Buy
Chem	292	38.87	9.37	24.06	33.43	11,349.17	9,761.56
Urinalysis	232	19.32	5.63	15.95	21.58	4,482.14	5,005.40
CBC	221	29.55	6.72	24.06	30.78	6,530.71	6,801.28
RPR	193	18.52	6.25	24.06	30.31	3,574.84	5,849.83
HCG	146	7.84	8.75		8.75	11,44.67	12,277.50
Throat cul	38	8.37	26.12	15.95	42.07	318.20	1,598.66
ESR	24	25.64	11.56		11.56	615.26	277.44
GC cul	22	8.38	24.70	15.95	40.65	184.45	894.30
Occult bld	20	7.37	31.60	15.95	47.55	147.40	951.00
Retic	20	35.41	23.80		23.80	708.17	476.00
Monospot	13	10.31	25.60		25.60	133.97	332.80
Urine cul	12	8.39	20.50	15.95	36.45	100.73	437.40
Wound cul	1	8.16	26.12	15.95	42.07	8.16	42.07
Total Annual Cost						$29,297.90	$33,705.24

Table 15.--Total Laboratory Cost - Make Versus Buy: Scenario 2

Test	Volume	Make	Buy	Overhead Associated With Buy	Cost To Buy Per Test	Total Cost To Make	Total Cost To Buy
Chem	624	18.42	9.37	11.93	21.30	11,496.18	13,291.20
Urinalysis	488	9.20	5.63	7.91	13.54	4,488.41	6,605.08
CBC	476	13.92	6.72	11.93	18.65	6,623.58	8,875.02
RPR	425	8.81	6.25	11.93	18.18	3,743.58	7,726.50
HCG	289	4.46	8.75		8.75	1,289.85	2,528.75
Throat cul	83	5.53	26.12	7.91	34.03	459.29	2,824.49
ESR	47	12.26	11.56		11.56	576.01	543.32
GC cul	44	5.54	24.70	7.91	32.61	243.70	1,434.84
Occult bld	45	4.56	31.60	7.91	39.51	204.98	1,777.95
Retic	25	19.29	23.80		23.80	482.28	595.00
Monospot	26	5.79	25.60		25.60	150.65	665.60
Urine cul	24	5.54	20.50	7.91	28.41	133.04	681.84
Wound cul	1	5.43	26.12	7.91	34.03	5.43	34.03
Total Annual Cost						$29,896.98	$47,583.62

Table 16.--Total Laboratory Cost - Make Versus Buy: Scenario 3

Test	Volume	Make	Buy	Overhead Associated With Buy	Cost To Buy Per Test	Total Cost To Make	Total Cost To Buy
Chem	729	15.87	9.37	10.48	19.85	11,569.86	14,470.65
Urinalysis	561	7.98	5.63	6.95	12.58	4,476.60	7,054.58
CBC	540	12.16	6.72	10.48	17.20	6,563.93	9,285.30
RPR	498	7.63	6.25	10.48	16.73	3,798.83	8,331.54
HCG	299	4.06	8.75	6.95	15.70	1,213.84	4,694.30
Throat cul	96	5.20	26.12	6.95	33.07	498.72	3,174.72
ESR	57	10.59	11.56	N/A*	11.56	603.39	658.92
GC cul	53	5.20	24.70	6.95	31.65	275.56	1,677.45
Occult bld	51	4.22	31.60	6.95	38.55	215.17	1,966.05
Retic	30	16.50	23.80	N/A*	23.80	494.98	714.00
Monospot	29	5.25	25.60	6.95	32.55	152.36	943.95
Urine cul	29	5.20	20.50	6.95	27.45	150.91	796.05
Wound cul	1	5.11	26.12	6.95	33.07	5.11	33.07
Total Annual Cost						$30,019.27	$53,800.58

* No overhead was allocated to the cost of buying ESRs and Retics because they are almost always ordered in conjunction with the CBC

Staff Utilization

The expected maximum personnel utilization is approximately 75 percent. If staff members work more than 75 percent of the day for extended periods of time, there is actually diminishing return on productivity. The models documented evidence that the laboratory technicians were being underutilized. Table 17 illustrates all technicians being underutilized in scenario 1 and

three technicians were underutilized in both scenarios 2 and 3. Using the modified model, staff members were idle most of the day. See Table 18.

Table 17.--Staff Utilization By Percentage

Staff Utilization	Scenario 1	Scenario 2	Scenario 3
Tech 1	37.34%	60.15%	67.27%
Tech 2	43.15	72.35	75.53
Tech 3	41.87	61.57	59.26
Tech 4	41.26	58.32	58.20
Tech 5	60.60	82.55	84.84

Table 18.--Staff Utilization By Percentage: Alternate Model

Staff Utilization	Scenario 1	Scenario 2	Scenario 3
Tech 1	11.72%	18.38%	20.19%
Tech 2	10.89	15.38	16.60
Tech 3	12.12	19.44	21.65

Equipment Utilization

The negotiated lease price for the automated equipment was based on an expected volume. Table 19 compares the estimated usage to the anticipated usage generated from the model. The Synchron CX5 Delta exceeded the monthly usage in scenario 2 and 3, but no specific cost data was available for this analysis. It was understood that the increased volume would generate a cost savings for the chemistry tests and that the total lease cost for the chemistry analyzer would increase. The model clearly illustrated that even with the FPG at full capacity, there is a large amount of excess capacity on both the Coulter MAXM and the Boehringer Mannheim Chemstrip ®.

Table 19.--Monthly Lease Agreement Cost Based On Projected Usage

Instrument	Monthly Projected Usage	Scenario 1	Scenario 2	Scenario 3
Synchron CX5 Delta	5000*	2920	6240	7290
Coulter MAXM				
CBCs	1200	221	476	540
Reticulocyte	100	20	25	30
Boehringer Mannheim Chemstrip ®	600	232	488	561

*analytes

Conclusion

The simulation model allowed one to easily analyze the amount of labor and other resources expended in the operation of the laboratory at BMCNTC. Based on the cost information listed in Table 10, it appeared that it was more cost effective to buy laboratory services since the high volume tests (chemistries, urinalysis, CBCs, and RPRs) were considerably cheaper. However, this did not take into consideration the need for clinic space in which patients have their blood drawn and could drop off their urinalysis and microbiology specimens. In the final analysis, clinic overhead had to be distributed to appropriate cost centers. The overhead that is allocated to the laboratory when it is performing testing should also be allocated to the same cost center when the laboratory testing is outsourced and the space is used only for specimen collection.

Taking this into consideration, Table 20 illustrates the annual budgets for the three scenarios. By allocating the clinic overhead when laboratory service is bought, it is readily apparent that the laboratory at BMCNTC should perform its own testing. If the volume of testing decreases to a level that is less than the amount assumed in scenario one, the decision to outsource service should be seriously considered.

Table 20.--Final Analysis

Annual Budget	Make	Buy
Scenario 1	$29,297.90	$33,705.24
Scenario 2	$29,896.98	$47,583.62
Scenario 3	$30,019.27	$53,800.58

The other component that should be considered is staff utilization. In all scenarios, there is excess laboratory capacity as staff members (and the laboratory equipment, designed for high volume), are being grossly underutilized. The technicians could be given additional clinic responsibilities, but this is not a viable option. During laboratory testing, there are frequent idle periods in which the technician waits for the analyzer to complete the test. If there are other specimens that can be processed, an efficient technician can do those activities during the idle time. If the technician is out of the clinic or otherwise distracted, there is great potential to make a mistake.

However, there is an opportunity to use this excess capacity. Laboratory tests that are currently performed at other locations could be analyzed at BMCNTC. There are four clinics in the San Diego area that perform laboratory testing. An analysis of those laboratories might give credence to the hypothesis that is cheaper to perform just specimen collection at one or more of those sites and use the laboratory at BMCNTC to perform this testing.

This analysis assumed that the prices for the reference testing were fixed and no further negotiations to discount the price have occurred. An analysis of this kind enables the clinic administrator to know what the true ACPRR given a particular volume. If a deeper discount can be obtained, one has the necessary data to make an informed decision.

Limitations Of The Study

This analysis was undertaken with the purpose of providing as much valid information as possible to determine the most accurate ACPRR at BMCNTC, however, this study is not without limitations. Very little data were available for analysis and numerous assumptions had to be made. Many patients have more than one test requested per phlebotomy. There were no data available to document the number of multiple tests ordered per patient so it was assumed that each patient has one request per phlebotomy. The net effect was to overestimate the amount of time required by the staff members and that was considered a preferable direction in which to err.

The limited data collection could affect the selected distributions and descriptive statistics. However, the modeler evaluated each reported variable in the output and made an evaluation of the validity of the result. If the output appeared erroneous, estimates from the observed data were used.

Equipment failures are a fact of life in any laboratory and they have a considerable impact on the staff 's ability to complete the day's required testing. There was no documentation available to quantify the amount of technician time that was used to get the analyzers functional after unscheduled failure. Since all the equipment is new and under full service contracts, the amount of unscheduled down time should be minimal and its impact limited.

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